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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,431	11/02/2001	Dennis J. Hlavinka	B0023-US01	8553

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GAMBRO, INC
PATENT DEPARTMENT
10810 W COLLINS AVE
LAKEWOOD, CO 80215

EXAMINER

SORKIN, DAVID L

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 07/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,431

Applicant(s)

HLAVINKA ET AL.

Examiner

David L. Sorkin

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 37-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-64 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-36, drawn to a centrifuge rotor, classified in class 494, subclass 45.
 - II. Claims 37-54, drawn to a plurality of interconnected containers, classified in class 422, subclass 102.
 - III. Claims 55-64, drawn to a method of centrifugation, classified in class 494, subclass 37.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination, for example according to claim 1, requires "a composite fluid containment area" and "collection area", which may be integral parts of the rotor; however, the subcombination requires distinct "containers" which are separable from a rotor. The subcombination has separate utility such as with a rotor that has only a single separated component collection area, rather than "first and second separated component collection areas". Also, the containers could be used without any rotor, for example to separate oil and

Art Unit: 1723

water gravitationally, or to mix two reactants stored in the two "containers" together in the "vessel".

3. Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, fluid could be loaded into a location other than that required by invention III.

4. Inventions II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus could be used to practice a method which does not require "first and second outlet channels" and "first and second separated component collection areas", but instead having only one out channel and one separated component collection area. Also, the apparatus could be used without a "peripheral separation channel", for example if the "separation vessel" is not located peripherally or is not channel-shaped. Also, fluid could be loaded into a location other than that required by invention III.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Art Unit: 1723

6. Because these inventions are distinct for the reasons given above and the search required for each Group is different, restriction for examination purposes as indicated is proper.

7. During a telephone conversation with Peter B. Scull on 29 May 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-36. Affirmation of this election must be made by applicant in replying to this Office action. Claims 37-64 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

9. The abstract is objected to because it is too long. 35 CFR 1.72 states "[t]he abstract filed under 35 U.S.C. 111 may not exceed 150 words in length".

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1723

11. Claims 1-30, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Joyce (US 3,747,843). Regarding claim 1, Joyce ('843) discloses a centrifugation configuration for centrifugally separating a composite fluid into component parts thereof, said configuration comprising a rotor (2,3) which includes a composite fluid containment area (9); a fluid inlet channel (26); a peripheral fluid separation channel (18,13A); first (11) and second (16) separated component outlet channels; and first (10) and second (15) separated component collection areas; wherein said inlet channel (26) is disposed in fluid communication with said fluid containment area (9) (see Fig 3); and wherein said peripheral separation channel (18,13A) is fluid communication with said fluid inlet channel (see Fig. 3) and said first (11) and second (16) separated fluid outlet channels (see Figs. 5 and 4, respectively); and wherein said first (11) and second (16) separated fluid outlet channels are disposed in fluid communication with said first (10) and second (15) separated component collection areas (see Figs. 5 and 4, respectively); and whereby said first (11) and second (16) separated fluid outlet channels also have respective first and second heights (see Fig. 1). Note that according to the instant specification "height" is the distance radially inward toward an axis of rotation, from an arbitrary circle with the axis at its center (see page 17 line 29 to page 18 line 9 of the instant specification). Note: alternatively channel 16 could be considered the "first" outlet channel and channel 11 the "second", and area 15 could be considered the "first" collection area and area 10 the second collection area. Claim 1 additionally recites "wherein said heights are related to each other so as to provide a substantial fluid balance for respective separated components flowing therethrough"; however, it is

Art Unit: 1723

considered that this recitation fails to further structurally limit the claimed apparatus.

This is because, as explained throughout the instant specification, for example on page 18 line 23 to page 19 line 17, the condition for balance depends upon the densities of the fluid and components thereof. As held in *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969), "[e]xpressions relating the apparatus to contents thereof are of no significance in determining patentability of the apparatus claim". The above-quoted additional recitation of claim 1 is analogous to requiring a seesaw to have the length of the two portions extending from the fulcrum be such that two people are balanced when sitting at the respective ends, without knowing the weights of the two people.

Furthermore, not only will the condition for balance depend upon the density of the fluid and components thereof, but also upon how full the channels and associated collection/containment areas are. For example, referring to instant Figs. 7 and 8, if area 42 contained fluid as shown in Fig. 7, the height h_1 would not be the determining factor of fluid pressure, because the liquid level in area 42 would need to be added to h_1 , while if any channel is less than full, the height of the channel would not determine pressure.

In summary, the above-quoted additional recitation of claim 1 is considered to be a recitation of how the claimed apparatus is intended to be used, rather than any structural limitation. As held in *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987), "recitation with respect to the manner in which the claimed device is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus". Likewise, depended claims 2-4, 6-11 and 13-16 are considered to only recite intended uses. While some of these claims specify the components therefore

satisfying the unknown density issues discussed above, the material level issue discussed above prevents even these claims from implying any structure. Claims 5 and 12; however, are considered to imply structure. Claim 5 requires that "the second separated component is a heavier component"; which is consistent with radially outward channel 11 being the "second channel" (see discussion of claim 1 above), while claim 12 requires that "the first separated component is a heavier component", which is consistent with radially outward channel 11 being the "first channel" (see discussion of claim 1 above). Regarding claim 17, Joyce ('843) discloses a centrifugation configuration for centrifugally separating a composite fluid into component parts thereof, said configuration comprising a rotor (2,3) which includes a composite fluid containment area (9); a fluid inlet channel (26); a peripheral fluid separation channel (18,13A); first (11) and second (16) separated component outlet channels; and first (10) and second (15) separated component collection areas; wherein said inlet channel (26) is disposed in fluid communication with said fluid containment area (9) (see Fig 3); and wherein said peripheral separation channel (18,13A) is in fluid communication with said fluid inlet channel (see Fig. 3) and said first (11) and second (16) separated fluid outlet channels (see Figs. 5 and 4, respectively); and wherein said first (11) and second (16) separated fluid outlet channels are disposed in fluid communication with said first (10) and second (15) separated component collection areas (see Figs. 5 and 4, respectively); and whereby said first (11) and second (16) separated fluid outlet channels and said fluid inlet channel (26) also have first, second, and third heights (see Fig. 1). Note that according to the instant specification "height" is the distance radially inward toward an

Art Unit: 1723

axis of rotation, from an arbitrary circle with the axis at its center (see page 17 line 29 to page 18 line 9 of the instant specification). Note: alternatively channel 16 could be considered the “first” outlet channel and channel 11 the “second”, and area 15 could be considered the “first” collection area and area 10 the second collection area. Claim 17 additionally recites “wherein said heights are related to each other so as to provide a fluid pressure forward flow drive force for respective composite fluid and the respective separated components flowing therethrough”; however, it is considered that this recitation fails to further structurally limit the claimed apparatus. This is because, as explained throughout the instant specification, for example on page 18 line 23 to page 19 line 17, the condition for flow or balance depend upon the densities of the fluid and components thereof. As held in *Ex parte Thibault*, supra., “[e]xpressions relating the apparatus to contents thereof are of no significance in determining patentability of the apparatus claim”. Furthermore, not only will the conditions for flow or balance depend not only upon the density of the fluid and components thereof, but also upon how full the channels and associated collection/containment areas are. For example, referring to instant Figs. 7 and 8, if area 42 contained fluid as shown in Fig. 7, the height h_1 would not be the determining factor of fluid pressure, because the liquid level in area 42 would need to be added to h_1 , while if any channel is less than full, the height of the channel would not determine pressure. In summary, the above-quoted additional recitation of claim 1 is considered to be a recitation of how the claimed apparatus is intended to be used, rather than any structural limitation. As held in *Ex parte Masham*, supra., “recitation with respect to the manner in which the claimed device is intended to be

Art Unit: 1723

employed does not differentiate the claimed apparatus from a prior art apparatus".

Likewise, depended claims 18-30 are considered to only recite intended uses. While some of these claims specify the components therefore satisfying the unknown density issues discussed above, the material level issue discussed above prevents even these claims from implying any structure. Regarding claim 34, Joyce ('843) discloses a composite fluid separation device comprising a rotor (2,3) having an axial, a radial and a circumferential orientation, wherein said rotor is rotatable about said axial orientation (see col. 3, lines 4-8); said rotor also having a substantially centrally disposed containment pocket (9); an inlet channel (26) in communication with said containment pocket; a peripheral channel (18,13A) communicating with said inlet channel; an outlet channel (11) communicating with said peripheral channel; and a collection pocket (10) communicating with said outlet channel; whereby the inlet channel has a respective height h_c and the outlet channel has a respective height h_1 and h_c is greater than h_1 (see Fig. 1). Note that according to the instant specification "height" as the distance radially inward toward an axis of rotation, from an arbitrary circle with the axis at its center (see page 17 line 29 to page 18 line 9 of the instant specification). Channel 26 of the reference is of greater "height" because it terminates more radially inwardly than channel 11. Regarding claim 35, the rotor further comprises a second outlet channel (16) communicating with said peripheral channel; and a second collection pocket (15) communicating with said second outlet channel; whereby said second outlet channel has a respective height h_2 ; and h_c is greater than h_1 or h_2 (see Fig. 2; both channel 11 and channel 16 terminate more radially inwardly than channel 26).

12. Claims 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by IBM Technical Disclosure Bulletin, vol. 17, issue 2, pages 404-405 ("IBM" herein). (Pages renumbered 1-3 on reprinted database copy provided with this office action). Regarding claim 34, IBM discloses a composite fluid separation device comprising a rotor having an axial, radial and a circumferential orientation; wherein said rotor has a circumference and is rotatable about said axial orientation (see Figs. 1 and 2; pages 1 and 2); said rotor having a substantially centrally disposed containment pocket (the region between the innermost two opposed semicircles, near the center of Fig. 2), an inlet channel (where the words "WHOLE BLOOD" appear in Fig. 2) communicating with said containment pocket; a peripheral channel communicating with said inlet channel (see sentence bridging pages 1 and 2 and see Fig. 2); an outlet channel (where an arrow and the word "PLASMA" appear in Fig. 2) communicating with said peripheral channel; and a collection pocket (where the words "PLASMA COLLECT VOLUME" appear in Fig. 2); whereby said inlet channel has a respective height h_c and the outlet channel has a respective height h_1 and h_c is greater than h_1 (see Fig. 2). Note that according to the instant specification "height" as the distance radially inward toward an axis of rotation, from an arbitrary circle with the axis at its center (see page 17 line 29 to page 18 line 9 of the instant specification). The "WHOLE BLOOD" channel of the reference is of greater "height" because it terminates more radially inwardly than the "PLASMA" channel. Regarding claim 35, the rotor further comprises a second outlet channel (the other of the twin "PLASMA" channels); and a second collection pocket (the other of the twin "PLASMA COLLECT VOLUME" pockets) communicating with said second outlet

Art Unit: 1723

channel; whereby h_c is greater than h_1 or h_2 (see Fig. 2). Regarding claim 36, , the rotor further comprises a second outlet channel (the other of the twin "PLASMA" channels); and a second collection pocket (the other of the twin "PLASMA COLLECT VOLUME" pockets) communicating with said second outlet channel; whereby the heights of the identical channels outlet channels are identical (see Fig. 2).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joyce (US 3,747,843) in view of Ontko et al. (US 3,304,990). Regarding claim 31, Joyce ('843) discloses a centrifugal separation device for use in a fluid separation system to centrifugally separate a composite fluid into composite components thereof,

Art Unit: 1723

said centrifugal separation device comprising a rotor having a composite fluid containment area (9) and at least one component fluid collection area (10); said rotor having a fluid inlet channel (26); a circumferential fluid separation channel (18,13A) and first and second separated component channels (11, 16); wherein said inlet channel (26) is disposed in fluid communication with said fluid containment area (9) (see Fig. 3); and wherein said circumferential separation channel (18,13A) is disposed in fluid communication with said fluid inlet channel and said first and second separated fluid outlet channels (11,16) (see Figs. 4 and 5); and wherein at least one of said first and second fluid outlet channels (11) is disposed in fluid communication with said at least one component collection area (10) (see Fig. 5); said first and second fluid outlet channels also having respective first and second heights (see Fig. 1). Note that according to the instant specification "height" is the distance radially inward toward an axis of rotation, from an arbitrary circle with the axis at its center (see page 17 line 29 to page 18 line 9 of the instant specification). Claim 31 additionally recites "wherein said heights are related to each other so as to provide a substantial fluid balance for respective separated components flowing therethrough"; however, it is considered that this recitation fails to further structurally limit the claimed apparatus. This is because, as explained throughout the instant specification, for example on page 18 line 23 to page 19 line 17, the condition for balance depends upon the densities of the fluid and components thereof. As held in *Ex parte Thibault*, supra., "[e]xpressions relating the apparatus to contents thereof are of no significance in determining patentability of the apparatus claim". The above-quoted additional recitation of claim 31 is analogous to

requiring a seesaw to have the length of the two portions extending from the fulcrum be such that two people are balanced when sitting at the respective ends, without knowing the weights of the two people. Furthermore, not only will the condition for balance depend upon the density of the fluid and components thereof, but also upon how full the channels and associated collection/containment areas are. For example, referring to instant Figs. 7 and 8, if area 42 contained fluid as shown in Fig. 7, the height h_1 would not be the determining factor of fluid pressure, because the liquid level in area 42 would need to be added to h_1 , while if any channel is less than full, the height of the channel would not determine pressure. In summary, the above-quoted additional recitation of claim 31 is considered to be a recitation of how the claimed apparatus is intended to be used, rather than any structural limitation. As held in *Ex parte Masham*, supra., "recitation with respect to the manner in which the claimed device is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus". Joyce ('843) fails to explicitly disclose a centrifugal drive motor base and a centrifugal rotor housing in which the rotor freely rotates. (Note that while Joyce '843 uses the term "rotor housing", the term is used to refer to an outer portion of a rotor, not a housing in which a rotor freely rotates). Ontko ('990) discloses a centrifugal drive motor base (15,47,40) and a rotor housing (11) (in which a rotor 27 freely rotates) positioned on the base. It is considered that it would have been obvious to one of ordinary skill in the art to have provided a motor base and rotor housing for the rotor of Joyce ('843) as taught by Ontko ('990), because Joyce ('843) states that the rotor should have a "motor drive" in column 3, lines 4-8 and a "centrifuge housing" in col. 4, line 26, without detailing the

specifics of these components. Regarding claim 32, Ontko ('990) further teaches that that centrifugal drive base produces a rotating magnetic field (see col. 3, lines 39-41) and a rotor having a magnetically reactive material which is adapted to rotate with the rotating magnetic field produced by said motor base, whereby said rotor is caused to rotate by the co-action of said magnetically reactive material and said rotating magnetic field (see col. 3 line 5 to col. 4 line 25). Ontko ('990) explains that such a magnetic drive provided the advantage of allowing the centrifuge to be explosion proof by isolating the housing from the motor (see col. 1, lines 45-56 and col. 3, lines 72-75). Regarding claim 33, the motor base of Ontko ('990) has a flat top surface (15); and the rotor housing has a flat bottom surface, whereby the flat top surface and the flat bottom surface co-act to provide the adaptation of the rotor housing to be disposed in operable position on said motor base (see Fig. 1).

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 703-308-1121. The examiner can normally be reached on 8:00 -5:30 Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

Art Unit: 1723

872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

A handwritten signature in cursive script, appearing to read "David Sorkin".

David Sorkin

May 30, 2003